

AMENDED IN ASSEMBLY MAY 8, 2006

AMENDED IN ASSEMBLY APRIL 4, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 2156

Introduced by Assembly Member Niello

February 21, 2006

An act to amend Section 1209.1 of, and to add Section 1209.5 to, the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 2156, as amended, Niello. Clinical laboratories.

Existing law provides for the licensure and regulation of clinical laboratories and their personnel by the State Department of Health Services. Existing law makes a violation of these provisions a crime.

Existing law defines a “histocompatibility laboratory director” as any person who is (1) a duly licensed physician, (2) a bioanalyst, or (3) a person who has earned a doctoral degree in a biological science and has completed, as specified, 4 years of experience in immunology, 2 of which have been in histocompatibility testing.

This bill would require an applicant for licensure as a histocompatibility laboratory director, *on and after January 1, 2007*, to successfully complete a written exam administered by the American Board of Histocompatibility and Immunogenetics and an oral exam administered by the department.

Existing law defines a “laboratory director” as any person that is a duly licensed physician and surgeon, or is licensed to direct a clinical laboratory and who meets specified qualifications. Existing law makes laboratory directors responsible for the overall operation and

administration of clinical laboratories which includes, among other things, the reporting of results.

This bill would require a laboratory director or a licensed authorized designee appointed by the laboratory director to establish, validate, and document explicit criteria by which clinical laboratory tests or examination results are autoverified, as defined. The bill would also require a laboratory director or an authorized designee, annually, to revalidate the criteria. The bill would require specified licensed persons to be physically present onsite in the clinical laboratory and it would make these specified licensed persons responsible for the accuracy and reliability of the results when they are autoverified and reported.

Because the bill would revise requirements pertaining to clinical laboratories and their personnel, a violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 1209.1 of the Business and Professions
- 2 Code is amended to read:
- 3 1209.1. (a) As used in this chapter “histocompatibility
- 4 laboratory director” means a person who has completed,
- 5 subsequent to graduation, four years of experience in
- 6 immunology, two of which have been in histocompatibility
- 7 testing, and who meets one of the following requirements:
- 8 (1) Is a licensed physician and surgeon.
- 9 (2) Is a bioanalyst.
- 10 (3) Has earned a doctoral degree in a biological science.
- 11 (b) ~~In~~ On and after January 1, 2007, in order to be eligible for
- 12 licensure as a histocompatibility laboratory director, an applicant
- 13 shall provide evidence of satisfactory performance on a written
- 14 examination in histocompatibility administered by the American

1 Board of Histocompatibility and Immunogenetics, and have
2 demonstrated satisfactory performance on an oral examination
3 administered by the department regarding this chapter and Part
4 493 (commencing with Section 493.1) of Subchapter G of
5 Chapter IV of Title 42 of the Code of Federal Regulations.

6 (c) A person licensed under Section 1260.1 as a
7 histocompatibility laboratory director and qualified under CLIA
8 may perform clinical laboratory tests or examinations classified
9 as of high complexity under CLIA and the duties and
10 responsibilities of a laboratory director, technical consultant,
11 clinical consultant, technical supervisor, and general supervisor,
12 as specified under CLIA, in the specialty of histocompatibility,
13 immunology, or other specialty or subspecialty specified by
14 regulation adopted by the department. A person licensed as a
15 “histocompatibility laboratory director” may perform any clinical
16 laboratory test or examination classified as waived or of
17 moderate complexity under CLIA.

18 SEC. 2. Section 1209.5 is added to the Business and
19 Professions Code, to read:

20 1209.5. (a) “Autoverification” means the use of a computer
21 algorithm in conjunction with automated clinical laboratory
22 instrumentation to review and verify the results of a clinical
23 laboratory test or examination for accuracy and reliability.

24 (b) The laboratory director or authorized designee shall
25 establish, validate, and document explicit criteria by which the
26 clinical laboratory test or examination results are autoverified.

27 (c) The laboratory director or authorized designee shall
28 annually revalidate the explicit criteria by which the clinical
29 laboratory test or examination results are autoverified. The
30 laboratory director shall approve and annually reapprove the
31 computer algorithm.

32 (d) An authorized designee shall be appointed by the
33 laboratory director for the purposes of this section. The
34 authorized designee shall be licensed to engage in clinical
35 laboratory practice pursuant to this chapter and shall be qualified
36 as a clinical consultant, technical supervisor, general supervisor,
37 or technical consultant pursuant to regulations adopted by the
38 department.

39 (e) A person licensed to perform the applicable type and
40 complexity of testing pursuant to Section 1206.5 shall be

1 physically present onsite in the clinical laboratory and shall be
2 responsible for the accuracy and reliability of the results of the
3 clinical laboratory test or examination when the results are
4 autoverified and reported.

5 SEC. 3. No reimbursement is required by this act pursuant to
6 Section 6 of Article XIII B of the California Constitution because
7 the only costs that may be incurred by a local agency or school
8 district will be incurred because this act creates a new crime or
9 infraction, eliminates a crime or infraction, or changes the
10 penalty for a crime or infraction, within the meaning of Section
11 17556 of the Government Code, or changes the definition of a
12 crime within the meaning of Section 6 of Article XIII B of the
13 California Constitution.